K082075
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SECTION 7

AUG 15 2008

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

510(k) Number:

Applicant Information:

Owner Name:	Hansen Medical, Inc.
Address:	800 East Middlefield Rd. Mountain View, CA. 94043 Office: 650-404-5800
Contact Person:	Kate Whitin
Phone Number:	650 404 5800
Facsimile Number:	650 404 5901
Date Prepared:	7/21/08

Device Information:

Classification:	Class II
Trade Name:	Hansen Medical Dilator for Artisan™ Control Catheter
Common name:	Dilator for Artisan Control Catheter
Classification name:	Vessel Dilator (21 CFR 870.1310, Product Code DRE)

Predicate Devices:

Hansen Medical Transseptal Needle and Dilator (K061070).

Device Description:

The Dilator for Artisan Control Catheter is made of a flexible tube with a tapered end on the distal outer diameter. A hemostasis valve and stopcock are attached on the proximal end. The Dilator has a through lumen for introduction over a guide wire.

Intended Use:
The Dilator for Artisan Control Catheter is intended to introduce the Artisan Control Catheter into the atria and through the intraatrial septum from the right side of the heart to the left side.

Comparison to Predicate Device(s):
The Dilator for Artisan Control Catheter has the same general intended use and similar technological characteristics as the predicate device. The indications for use is confined to the role of the dilator without the needle.

Substantial equivalence:
The Dilator has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the Dilator and its predicate device raise no new issues of safety or effectiveness. Based upon this pre-market notification, the Dilator is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 15 2008

Hansen Medical, Inc.
c/o Ms. Kate Whitin
Director, Regulatory Affairs
800 Middlefield Road
Mountain View, CA 94043

Re: K082075
Trade/Device Name: Hansen Medical Dilator for Artisan™ Control Catheter
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator
Regulatory Class: Class II
Product Code: DRE
Dated: July 22, 2008
Received: July 23, 2008

Dear Ms. Whitin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality

systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 6

Indications for Use

510(k) Number (if known):

Device Name: Hansen Medical Dilator for Artisan™ Control Catheter

Indications for Use:

The Dilator for Artisan™ Control Catheter is intended to introduce the Artisan Control Catheter into the atria and through the intraatrial septum from the right side of the heart to the left side.

Prescription Use _x_ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices